



REPORTING GUIDELINE:
EXAMPLE FORMAT FOR THERAPY MEDICAL EVENTS

Therapeutic radiation machines in Michigan have registration conditions which require that therapy medical events be reported in writing within 30 days to the Michigan Department of Licensing and Regulatory Affairs, Radiation Safety Section, any event, except for an event that results from patient intervention, in which the administration of therapeutic radiation:

- (1) Results in the total dose delivered differing from the prescribed dose by 20% or more; or
- (2) Results in any single delivered fraction of a fractionated treatment exceeding the prescribed dose by 50% or more; or
- (3) Involves the wrong patient, wrong treatment modality, or wrong treatment site.

The reporting of a therapy medical event pursuant to the registration condition should contain the elements listed below. Other formats are also possible and acceptable. Each item below should be on a separate line or should constitute a separate paragraph or paragraphs.

1. The date this report is prepared.
2. The facility name and address (as it appears on the registration certificate).
3. The facility registration number and machine registration number.
4. The date the medical event occurred.
5. The date of discovery of the medical event.
6. The name of the prescribing physician.
7. A brief narrative description of the event and its cause.
8. The effect, if any, on the individual(s) who received the administration.
9. A narrative detailing corrective action taken or planned to prevent a recurrence.
10. Certification that the registrant notified the individual (or the individual's responsible relative or guardian) and if not, why not.
11. Name and signature of individual preparing this report.

The report should not contain the individual's name or any other information that could lead to the identification of the individual.

The medical event report can be submitted to the Department by any one of the following methods:

Mailed to: Michigan Department of Licensing and Regulatory Affairs
BHCS/Radiation Safety Section
1st Floor, Ottawa Building
611 West Ottawa Street
Lansing, Michigan 48933

E-mailed to: rssinfo@michigan.gov

Faxed to: (517) 241-1981

If additional information is needed, contact the Lansing office of the Radiation Safety Section at (517) 241-1989, or the Detroit district office at (313) 456-4660.